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DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Disease Control and Prevention [30Day-20-19BPL]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Aerosols from cyanobacterial blooms: Exposures and health effects in a highly exposed population, to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on September 19, 2019 to obtain comments from the public and affected agencies. CDC received 162 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to comb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Aerosols from cyanobacterial blooms: Exposures and health effects in a highly exposed population - New - National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Algal toxins from cyanobacterial harmful algal blooms (CyanoHABs) include some of the most potent natural chemicals. People and animals are at risk for exposure to toxins produced by CyanoHABs in recreational waters, drinking water sources, or in improperly treated water used for medical purposes such as renal dialysis. Additional potential exposure sources include contaminated dietary supplements or fish harvested from lakes with ongoing CyanoHABs.

Although outbreaks of human illness associated with CyanoHABs were sporadically recorded for decades, information about clinical signs and symptoms from cyanobacterial toxin poisonings is primarily from animal poisonings and laboratory studies. The primary effects include acute hepatotoxicity, acute neurotoxicity, gastrointestinal symptoms, and respiratory, dermatologic, and allergic reactions.

A significant source of cyanobacterial toxin exposure is recreational use of contaminated fresh water bodies because

large populations are likely to be exposed and toxins may occur in high concentrations. In the United States, the U.S.

Environmental Protection Agency (EPA) provided guidance, but not regulations, on acceptable levels of the cyanobacterial toxins, microcystins and cylindrospermopsin, in drinking and recreational waters. Data from epidemiologic studies designed to evaluate the associations among environmental cyanobacteria toxin concentrations, human biomarkers of cyanobacteria toxin exposure, and health symptoms are needed to develop more specific exposure guidelines.

In addition to cyanobacterial toxins, other chemicals produced by cyanobacteria, such as geosmin and methylisoborneal (MIB), may be present in aerosols generated during a CyanoHAB. Geosmin and MIB produce a musty odor and taste in water that is noticeable at very low concentrations. CyanoHABs may present additional health risks as they die off and release hydrogen sulfide and methane into the air.

The National Center for Environmental Health (NCEH),

Centers for Disease Control and Prevention (CDC), requests a

three-year Paperwork Reduction Act (PRA) clearance for a new

information collection request titled "Aerosols from

cyanobacterial blooms: exposures and health effects." NCEH is

authorized to conduct research under the Public Health Service

Act, Section 301, "Research and investigation," (42 U.S.C. 241).

We will conduct a cohort study of 200 people highly exposed to CyanoHABs in Florida. We define "highly exposed" as those exposed because of their occupation (e.g., lock gate keepers, fishing guides) and those exposed because they live on a canal or river and spend at least two hours outside on most days. Bloom composition and concentrations of toxins can vary over time during a bloom and CDC is interested in not only exposure, but also how exposure varies as the blooms develop, mature, and die off. We cannot predict when or where a bloom may occur. Thus, we will work closely with the Florida Department of Environmental Protection to identify when a bloom develops. Once a bloom is verified, we will initiate the study (i.e., recruit and enroll participants) in the area affected by the bloom. We will collect data on five study days for each participant during the bloom season (approximately March - November). The estimated annual burden requested is 1273 hours.

Estimated Annualized Burden Hours

Type of	Form Name	Number of	Number of	Average
Respondents		Respondents	Responses	Burden
			per	per
			Respondent	Response
				(in
				hours)
Interested	Screening/Baseline	84	1	15/60
community	Survey			
members				
Eligible	Symptom Survey	67	10	15/60
study				

respondents				
Eligible	Record of Time	67	5	10/60
study	Spent Outdoors			
respondents				
Eligible	Provide Blood			
respondents	Specimen	67	3	15/60
Eligible	Provide Specimens			
respondents	(urine, nasal			
	swabs, lung			
	function test)			
		67	10	1
Eligible	Be Outfitted with			
respondents	Personal Air			
	sampler	67	5	45/60
Eligible	Provide Fish (if			
respondents	respondent went			
	fishing and caught	67	5	10/60
	fish)			

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